REMARKS

Rejections under 35 U.S.C. 102 (b)

The Examiner has rejected claims 16-26 under 35 U.S.C. 102 (b) over Cheung et al. The Examiner states that Cheung, et al. disclose a method of treating epilepsy by orally administering the compound CGP33101. The Examiner states that a Chemical Abstract (i.e. "CA" as cited by the Examiner) discloses that the structure is identical. The Applicants disagree with the Examiner and respectfully request that the Examiner withdraw the rejection based on these grounds.

The Examiner states that the chemical structure of CGP33101 is identical to the compound claimed in the present invention and therefore that this is an old product. However, the polymorphic modifications of the compounds disclosed in the present application are novel, non-obvious, and patented, in US Patent No. 6,740,669. US Patent No. 6,740,669 was drawn from the same priority filing as the present application and is noted on the Applicants' form 1449 which was submitted on April 12, 2004 in the present case. In US 6,740,669, the Applicants claim polymorphic modifications of a compound per se and in the present application the Applicants claim a method of using the novel and unobvious polymorphic modifications of the compound.

The Examiner further states that polymorphs have no merit on physiological applications since the polymorphs, in the physiological environment used in a therapeutic application, are amorphous and therefore that the employed forms in a physiological environment are identical. The Examiner cites a reference, Ulicky and Kemp, Comprehensive Dictionary of Physical Chemistry, and states that the reference indicates that in aqueous phase, all physical forms are amorphous. The Applicants disagree with the Examiner's characterization of Ulicky since the claimed polymorphic structures of the compounds have been found to be novel, non-obvious, and patentable. These findings are also supported by the X-ray powder diffraction that characterize the polymorphic structures. Thus the process of using the novel and non-obvious polymorphic modifications as a treatment could not have been anticipated if the polymorphic modifications themselves were not known to one of ordinary skill in the art. Further, the Applicants believe that the Examiner's characterization of Ulicky and Kemp is not accurate. Ulicky and Kemp does state that "[p]lasmas, gases, and liquids are always in an amorphous state...." However this characterization refers to the physical state of a substance itself and not

whether the substance is dissolved in solution. The liquid state referred to by Ulicky and Kemp exists when the substance is *melted* and non-crystalline and is irrespective of an aqueous environment. The Applicants claim the use of a novel and non-obvious *powdered* polymorphic substance to treat a patient. The physical state of relevance for the polymorphic compounds of the present invention is a solid and not a true liquid, gas or plasma. Thus, the statement made by Ulicky and Kemp, that is relied upon by the Examiner, is not applicable to the present case. The polymorphic form of the compound that would be administered to a patient according to the present invention would be a solid or have the properties associated with a solid that is dissolved – but not melted. Thus the novel and non-obvious polymorphic modifications of the crystalline solid would remain intact and applicable for the use claimed in the present application. Based on the foregoing, the Applicants respectfully request that the Examiner withdraw the rejections of claims 16-26 under 35 U.S.C. 102 (b) over Cheung et al.

Rejections under 35 U.S.C. 103 (a)

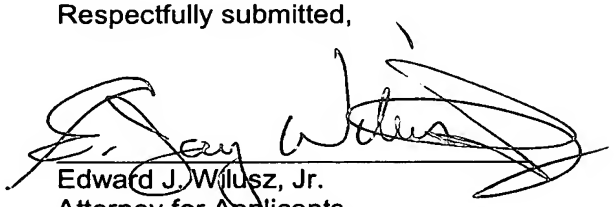
The Examiner rejects claims 16 – 26 under 35 U.S.C. 103 (a) over Cheung, et al. in view of Chem. Eng. News pp. 32-34 (2003) and also CA 108, 106, 105, 104, 101, 95, 94, 90, and 80. The Examiner also indicates that Cheung et al. disclose a dosage of CGP33101 of 400 mg. and the Applicants disclose 20 – 500 mg. The Applicants disagree with the Examiner and respectfully request that the rejection be withdrawn. Dosages disclosed in the in the present application can not be compared with the Cheung et al. reference, or any of the cited references, since the polymorphic modifications disclosed in the present application are novel, non-obvious and patented as described above. The process of using a polymorphic modification of compound, which polymorphic modification was not known to one skilled in the art can not be obvious (see In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed Cir 1995)). Therefore, the fact that Cheung et al, disclose a range of dosages which are similar to the Applicants' range is not relevant because the Applicants use novel and non-obvious polymorphic modifications which structure and benefits were not known to Cheung et al. nor to one skilled in the art at the time of filing the application. Even if the reference, Chem. Eng. News (2003), and the additional references cited by the Examiner, identify that different polymorphs can have different bioavailability, this does not alter the fact that the Applicants' process of using a novel and non-obvious polymorphic modification of a compound, for a method of treatment, is non-obvious in itself. Based on the foregoing, the Applicants respectfully request that the Examiner withdraw the rejection of claims 16 – 26 under 35 U.S.C. 103 (a) over Cheung, et al. in view of Chem. Eng. News pp. 32-34 (2003) and also CA 108, 106, 105, 104, 101, 95, 94, 90, and 80.

Based on the foregoing, the Applicants believe that the application is now in condition for allowance and respectfully request early notice to that effect.

If the Examiner deems that additional fees are properly assessable in the case or that certain fees should be refunded, the Examiner is authorized to charge or credit such fees to Deposit Account No. 19-0134 in the name of Novartis Corporation.

If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,



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